

IEEE PSES
20TH ANNIVERSARY

IEEE
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PROGRAM AT A GLANCE

KEYNOTE SPEAKER

Changing the Compliance Paradigm in Large Global Companies



Peter Shearstone, Thermo Fisher Scientific - Vice President, Global Quality & Regulatory Affairs

Compliance, quality and safety are in the news – and the subject of discussion in corporations and regulatory agencies around the world – like never before. At the same time, customers are seeking better products, while companies want greater collaboration, faster time to market and higher efficiency without affecting compliance or quality. While the Compliance function has evolved and is firmly established at more companies, it's still often in a reactive posture with late-stage involvement in the product development cycle, creating a significant opportunity.

In this keynote presentation, you'll learn how to seize that opportunity by changing the compliance paradigm across a large, global company.

The keynote will be delivered by Peter Shearstone, Vice President of Global Quality & Regulatory Affairs at Thermo Fisher Scientific, a company with 18 different businesses in life sciences solutions, specialty diagnostics, analytical instruments and laboratory products, and biopharma services, operating throughout the world with annual revenues of over \$40 billion.

Based on the experience, knowledge and insights gained during a career spanning more than 30 years in quality and regulatory affairs leadership roles at six companies in the life sciences, diagnostics and health care industries, Shearstone will provide a suggested roadmap on how to approach the formidable challenge of changing the compliance paradigm in a complex, international organization.

He'll also discuss the need to show how earlier Compliance involvement can positively affect business results, the importance of Leadership support, developing understandable policies, processes and roles, effective directed learning, impactful communications and measuring success.

When the paradigm is changed, Compliance can become a greater contributor to the product development process, be received as an indispensable partner for success, reduce the amount of time to receive compliance and go to market, and provide customers with better products, faster.

COMPLIANCE 101/201

Origins and Basics of Electrical Fire and Shock

Mike Sherman (Sherman PSC LLC)

The basic needs for fire and shock protection for electrical equipment emerged during a tumultuous period in the late 1880s and early 1890s. This presentation looks at that history, summarizes current best protection practices, and adds some hard-earned lessons from 30 years of electrical product safety work experience.

Misquoting Jargon: the Speculation on Weird Alterations of Standard Texts and Why

Lingfeng Chen (CSA)

With three case studies, this paper argued that behind those weird alterations of standard texts, there were good intentions to perfect standard texts. Nevertheless, by mistaking a near jargon, misquotation occurred. The source of misquotation and root cause behind the failure of correction were speculated. A more open and inclusive information sharing mechanism on the formation of standard texts was then advocated as a practicable solution.

Achieving Product Safety through Positive Human Interaction: Humans, Humor, and Getting Things Done

Mike Sherman (Sherman PSC LLC)

Persuasive communication skills make our product safety and compliance (PSC) jobs easier. Concise, pithy, and humorous sayings break the ice to help us focus on and solve product safety problems. This presentation provides time tested sayings, insights and philosophies to help you become a more effective product safety professional.

PSES Tutorial: Part 1: Compliance 101

Ken Kapur (Thermo Fisher Scientific)

Part 1: The intent of this presentation is to provide a basic knowledge of Product Safety and Regulatory Compliance for products sold worldwide. The presentation covers the requirements for those involved in new and existing products and those who need to address global safety requirements. This training will provide the fundamental guidance for product safety which can support geographic sales for import and export around the world.

COMPLIANCE 101/201 (CONT'D)

PSES Tutorial: Part 2: Compliance 201

John Allen (Product Safety Consulting, Inc.)

Part 2: This presentation is a continuation of presentation #1 (covering Product Safety and Regulatory Compliance for products sold worldwide), looking into the requirements in more detail. We will review requirements in product safety standards and the impact to new designs. Understanding the level of product safety testing in accordance with safety standards will also be covered. We will discuss product safety risks (Electrical, Mechanical, Lasers, Radiation, etc.) and methods to mitigate risk and ensure compliance. 'Design For Compliance' techniques will be discussed as they pertain to complying with global product safety standards (UL, CSA, IEC). Maintaining compliance through product modifications will be included. Challenges and best practices will be shared that will help product designers get a new product to market quickly and efficiently.

PSES Tutorial: Part 3: Global Market Access

Grant Schmidbauer (Nemko)

Part 3: Once your product complies with (all) the regulatory requirements for the different countries you plan to market the product, you must then obtain the necessary country approvals. This presentation will provide an overview of global market access requirements, and then give more specific requirements for North America, European Union, and some of the other Asian and South American countries.

Determining safety compliant components - Breaking the mystic!

Maria Martinez (Intertek)

What's a safety critical component, a common challenge among safety compliance engineers? This paper provides an overview of critical safety parameters and examples to demystify component selection, qualification and other performance requirements for an effective safety certification outcome.

Basics to sanitation certification

Brunno Covolan (Intertek)

Sanitation evaluation is a critical step in the certification process for appliances handling foods. Often, attention is given to electrical safety, but the nuances of sanitation requirements are missed. This presentation will provide an introduction to basic sanitation requirements, highlighting area requirements, construction requirements, proper material utilization, and commonly missed issues.

COMPLIANCE 101/201 (CONT'D)

Efforts to improve the quality and efficiency of product safety evaluation as a certification body

Ryota Naganuma (Cosmos Corporation)

Cosmos corporation has been making efforts to improve quality and efficiency of product safety evaluation as a certification body. Workflow, insulation structure diagram and checklist were created to achieve more accurate and sufficient evaluation against the safety standard. Our efforts will contribute to furthermore product safety in the world.

Risk Assessment: When have you reached Acceptable Risk?

Wylie Wong (Engineering Systems Inc.); **Anne Mathias** (Engineering Systems Inc.); **James Smolka** (Engineering Systems Inc.); **Joseph Mohorovic** (Engineering Systems Inc.); **Erick Knox** (Engineering Systems Inc.)

One of the primary goals of design is a product with acceptable risk, not zero risk. Methodologies for evaluating risk include following safety standards, benchmarking similar scoring systems, considering utility and intended use, and estimating risk with functional safety approaches. Developers can follow the guidance that best match their situations to determine when they have reduced risks sufficiently.

Fundamentals of Laser Safety – Part 1 – The Basics

Regan Arndt (Thermo Fisher Scientific)

This presentation provides an overview of what every person needs to know when handling all classes of lasers. Topics include: •General knowledge of laser safety fundamentals and terminology. •Awareness of biological hazards associated with laser processes. •Understanding of the laser standards applicable to their industry. •Familiarity with beam hazards in laser operation. •How to prevent industrial laser accidents through control measures. By the end of the presentation, you will be better informed about how to implement a laser safety program.

Fundamentals of Laser Safety – Part 2 – Laser Product Compliance

Gus Anibarro (GCA Laser Safety)

This presentation provides an overview of the FDA's CDRH regulations. Topics include: • Examples of laser product failures. • Overview of the US Federal Laser Product Performance standard. • Performance requirements–what features must absolutely be on the laser. • Labeling requirements–what to look for. • Informational requirements–what must be in the user manual. By the end of the presentation, you will be better positioned to ensure your laser is compliant with the FDA/CDRH.

How to Analyze a Schematic for Safety Compliance

Thomas Smith (Fluke Corporation)

When evaluating products for safety compliance, many organizations avoid testing and instead qualify products through component certification and construction. This presentation provides guidance on adding circuit analysis and single fault analysis to the safety compliance evaluation. Evaluating the consequences of critical component faults can keep the user safe.

COMPLIANCE 101/201 (CONT'D)

Circuit Spacings – Determining Product Safety Requirements

James Bender (Intertek); **Maryam Mahmoodi** (Intertek)

Circuit spacings is a key element to minimizing electrical shock and fire risks, critical for safe product development. This publication provides simplified guidelines to help understand, navigate, interpret and apply circuit spacings, which contributes towards a successful certification experience.

Fundamentals of Risk Assessment – Part 1

Regan Arndt (Thermo Fisher Scientific)

This session will provide an overview on assessing potential risks associated with a specific product throughout its lifecycle, from development to disposal. It begins with identifying and analyzing potential hazards, vulnerabilities, and uncertainties that could impact the safety of the product, the user, and the environment.

Fundamentals of Risk Assessment – Part 2

Mark Pearson (Thermo Fisher Scientific)

Part 2 provides an understanding of the elements of Risk (Severity, Frequency, Probability, Avoidance, and Likelihood) when conducting a proper product safety risk assessment. This session will help you identify and prioritize potential safety risks, which can assist in implementing appropriate mitigation strategies to ensure compliance with relevant regulations and standards.

Integrating Wireless Technology into Products

Theresa Glenna (TUV SUD)

Adding wireless technology to a product adds layers of certification requirements which can be challenging to navigate. Learn about different methods of integrating wireless modules and leveraging a pre-approved module. Take home some strategies to refine your compliance plan and ways to make informed decisions to save costs and manage your time to market.

COMPLIANCE 101/201 (CONT'D)

Live to LOVE your CB report

Lars Mellander (Nemko)

A VERY specific, interactive and detailed review of best practices and what you must know when requesting or starting a CB report/certification process. This may seem “basic” but after 20 years in the industry, I rarely see a CB report that could not be made better. The CB report is possibly the most valuable asset we have in the compliance industry, and absolutely critical that you are aware of how to get the most value for your money. You think you know everything there is to know about a CB report? Come to the presentation and see if you really do!

Independent Studies—Creating a Personal Curriculum for a Successful PSC Career

Mike Sherman (Sherman PSC LLC)

Our PSES Tutorials explain how to do product safety/compliance; this presentation explores what to know—from basic scientific and engineering concepts to higher level skills—to succeed.

Because your knowledge needs are dictated by your specific products, this presentation takes a checklist approach, so you can build your personal curriculum.

Historical product safety recall trends, analysis and exploratory overview

Chintan Trivedi (Intertek)

Exploratory analysis of reported recalls, impact to technology and product safety compliance. Paper provides a deep dive analysis of product safety recall data, trends and hazards overview including correlations and causations of changing technology and its impact to product safety.

ENERGY STORAGE AND BATTERIES

Coin cell safety – Reese’s Law requirement update

Ted Eckert (Microsoft)

There are new laws in a number of countries that impose additional requirements on products that contain coin/button cells. Reese’s Law in the United States was enacted in 2023 and has among the strictest requirements in the world. This presentation will go over the history of the law, its rationale, and the new requirements.

Deciphering UN 38.3: Updates and Interpretations

Rich Byczek (Intertek)

The UN 38.3 Transportation tests for Lithium and Lithium Ion batteries are a global requirement for all producers, assemblers and distributors of Lithium Batteries and Battery-Powered Devices. These tests are similar in nature but different in purpose than UL and IEC Products Safety tests. This session provides the most recent and expected updates to the UN 38.3 test regime, focusing in common misconceptions, and provides interpretations of failure modes and test applicability.

EU Battery Regulation Update

Ibrahim Jilani (UL Solutions)

Provide update on EU Battery Regulation. Summary available on <https://www.ul.com/insights/industry-insights-eu-battery-regulation-20231542>

Understanding the Risks Posed by User Replacement of Non-OEM Batteries

Keith Beers (Exponent)

With the proliferation of consumer electronic devices without user-replaceable batteries, there has also grown a market for the replacement of OEM batteries with third-party / non-OEM ones. Regardless of device, there exist numerous options for consumers looking for DIY options. Often the batteries used for this purpose are not supported by the device OEM and may include numerous differences, including different manufacturers, quality, designs, and certification testing. In this presentation, we will examine several third-party/non-OEM batteries and review them against common industrial practices, such as those listed in IEEE 1725. We will explore the battery design, manufacturing quality, and response to select tests. The discussion will be relevant to other consumer electronic devices such as laptops, tablets, and the like. We will also discuss potential risks for user replacement of batteries, and factors to consider when designing products to account for this potential use case.

Unveiling Trends in the Battery Industry: Insights from Third-Party Testing

Chara Diaz (Element Materials Technology)

In the ever-evolving landscape of battery technology, staying ahead of industry trends is imperative for manufacturers, developers, and OEMs. Third-party testing provides a unique vantage point, enabling a comprehensive analysis of various form factors, chemistries, and sizes, rather than focusing on a singular product for a specific OEM.

New EU Battery Regulation Primer

Jody Leber (CSA Group)

Explore essential requirements of the EU Battery Regulation and steps to assist manufacturers with compliance. Regulation Procedure 2020/0353/COD will formally take effect on February 18, 2024 - officially replacing the Battery Directive of 2006. While the original intention of this legislation was to establish a circular battery market by enforcing sustainable procurement and disposal practices, the final version has evolved to encompass a much broader in scope. In addition to circularity requirements, the regulation also introduces specific rules governing various types of batteries, including electric vehicle batteries, energy storage systems, and e-bike batteries. Furthermore, it imposes stricter production parameters for manufacturers looking to sell batteries within the EU market.

ENERGY STORAGE AND BATTERIES: ACCEPTED TO WAITLIST

Applications of Autonomous Battery Management System for Protecting Unmanned Aerial Vehicles

Maggie Hoang (Cal Poly Pomona Electrical and Computer Engineering)

This paper dives into the design of the complete autonomous system for replacing lithium-polymer batteries of small-scale UAVs improving extended flight times and preventing battery damages for aerial safety. The Robotic Ground System's (RGS) development focuses on a quick-charge power station to provide extensive flight time and eliminate long charging disturbances during ongoing missions. The Ground Control Station (GCS) has a well-designed locking mechanism that provides the drone with wireless charging technology essential to prepare the drone's hot-swapping procedure. The main core mechanic of the RGS, the "Battery Vending Machine" relies on a circular rotating battery compartment, tasked to store, manage, and distribute eight drone-compatible batteries when required. A robotic arm and Pod work together to transfer the battery from the two systems in a smooth matter. Accompanied by solar panels, its power comes from the sun's renewable energy, providing power to the entire system.

Characterizing Safety of Commercial Sodium and Lithium-ion Cells

Dhevathi Rajan Rajagopalan Kannan (UL Research Institutes); **Vinay Premnath** (UL Research Institutes); **Judy Jeevarajan** (UL Research Institutes)

This study focuses on the comprehensive characterization of the safety aspects of commercial Sodium-ion (Na-ion) and Lithium-ion (Li-ion) cells. The primary objective is to evaluate the safety performance of Na-ion and Li-ion cells under various stress conditions. The research encompasses a series of safety tests, including overcharge, overdischarge, and external heating using a tape heater. The results of this study provide valuable insights that can help in the development of safer and more reliable energy storage solutions for a range of applications, from portable electronics to electric vehicles and renewable energy storage systems. Understanding the safety profiles of these technologies is crucial for advancing the state of the art and ensuring the well-being of users and the environment.

FORENSICS

Design, Risk, and Efficacy While Testing to Standards – Tradeoffs for Surge Protective Devices

Eric Schultz (Engineering Systems Inc); Louis Bilancia (Engineering Systems Inc.); Thomas Bajzek (Engineering Systems Inc.)

Nationally Recognized Test Laboratories cannot anticipate all misuse and failure modes of a new product. This paper discusses a case study on Metal Oxide Varistor hazardous failure effects, testing of surge protection devices and whether the user gets the expected transient protection, and safe design considerations.

Not Worth a Nickel! A Nickel Metal Hydride Battery Failure Investigation

Brian May (ESi)

An energetic event in a nickel-metal hydride battery cell resulted in the failure of the product powered by the battery and the battery itself. During this presentation, the methodology used to diagnose the failure mode and a review of battery materials, chemistry, and appropriate standards will be discussed.

Navigating Consumer Product Safety: Engineering and Human Factors Insights

Emanuele Grossi (Exponent); **Daniel Palac** (Exponent)

Navigating consumer product safety often requires engineering and human factors considerations to determine overall risk of injury, understand user behavior, and assess and investigate regulatory issues and compliance. Using practical examples, this presentation provides engineering and human factors insights into consumer product development and failure analysis focused on product safety.

SAFETY SCIENCE & HBSE

IEC & EN 62368-1 – Navigating multiple editions of IT/AV standard – Strategies and Solutions

Grant Schmidbauer (Nemko North America, Inc.)

With the many different editions of the two standards, what should manufacturers do, also taking into account the 4th ed. of IEC 62368-1 just recently published. This session will give an overview of the different IEC and EN (European) versions of 62368-1, and then delve into the European system for CE marking for LVD when considering a harmonized standard (giving presumption of conformity) vs using a standard that is not harmonized to the OJ. The presentation will provide many useful web links and a glossary of terms.

Proposed National Differences for Canada and the U.S. Associated with Edition 4 of CSA UL 62368-1

Thomas Burke (UL Solutions)

In Canada/U.S. it is expected CSA UL 62368-1 Ed. 4, based on IEC 62368-1:2023, will be published as a CAN/US bi-national standard in 4Q 2024. This presentation reviews the key changes to the national differences, many of which were driven by the 2023 edition of the National Electrical Code (NEC).

Developing the Dynamic Hazard-Based Safety Engineering (D-HBSE) by Introducing the Control-Oriented Model

Shun Zhang (Cisco Systems); Haiwen Lu (Cisco Systems)

Traditional safety engineering approaches (reliability-oriented) were developed for relatively simple electro-mechanical systems, but new technology and functional requirements rapidly emerged, meanwhile, with the embedded systems and novel sensors that have been wildly applied, the interaction between hardware and software, as well as the corresponding design complexity exponentially increased, so the control-oriented model should be introduced to adapt the changed nature. This paper will illustrate why it is necessary to introduce the control-based model to hazard-based safety engineering (HBSE), based on a typical large core switching fan-tray architecture design and related failure model. Besides, the authors also provide detailed design and evaluation guidelines, which can ensure the control of random hardware failure and avoid systematic failure (both hardware and software), then achieve the safety target (i.e., safety integrity level).

GLOBAL MARKET ACCESS

Wireless Type Approvals and select country updates

Maja Bland (UL Solutions)

We will cover key concepts of market access radio spectrum control, requirements for type approvals. I will explain how leveraging test reports and certifications of radio modules can help save costs on testing and certifications of host (integrator) products. We will cover family approvals concept definitions and what that means for type approval process. Lastly, I will provide a summary update of the most recent China SRRC testing and certification changes. There will be time for Q and A and I look forward to continued conversation around Global Market Access requirements.

Global Regulatory Approvals: Beyond Certification with an emphasis on labeling

Peter Grinager (Approve-IT Inc.)

We'll review the topics below and add several detailed label case studies to discuss how labeling the product itself can be avoided and where alternate locations are available. Product Roadmaps, Think Global Testing, Distribution Hubs, Design Ownership, Labeling, Larger Organizational Involvement, Managing Renewals, The Importance of the Technical File, Standards Updates, Protecting Products from Regulatory Changes.

Regulatory For MENA Region

Lars Mellander (Nemko)

Over the last few years, there appears to be a much greater need for MENA based certifications. Certifications and type approvals that have been "required" for years, are now becoming a must to obtain or at least consider. This presentation provides the reasons for the recent growth in this requirement, detailed and specific information in regard to requirements and best practices to gain market access to the MENA region.

Indian Regulatory Demography - An overview on Electrical & Electronics segment

Saibal Mukhopadhaya (CSA Group, Canada)

In the light of recent and ever changing complex regulatory demography of India, this talk encompasses an overview of various regulatory schemes in the Electrical, Telecom and Electronics products segments. The presentation will provide a snapshot for Global manufacturers and investors on recent regulatory requirements under BIS's Compulsory Registration Scheme, TEC/WPC registration, BEE and PESO approval process in light with "Make in India", an India Government initiative.

6GHz adoption and challenges in Latin America

Elizabeth Perrier (ORBIS Compliance)

This presentation will show the rate of adoption of 6GHZ in Latin America and the discrepancies in regulations across the continent which block adoption. This is a technical discussion with practical examples that allow manufacturers to have full clarity of the regulatory obstacles.

GLOBAL MARKET ACCESS (CONT'D)

FCC and ISED certification requirements

Julia Gresser (CSA Group Bayern GmbH)

The FCC (USA) and ISED (Canada) certifications are helpful and sometimes even necessary, especially if you want to sell your product with radio functionalities globally. In this presentation, I would like to give you details about the certification process for radio products in USA and Canada and define the requirements.

China regulations update

Paul Wang (G&M Compliance, Inc.)

This presentation updates the latest regulations of China certifications. For CCC certification it will cover product category change and standards update for electrical products. For SRRC type approval it will introduce regulations about IPv6, 2.4GHz, 5.1GHz, 5.8GHz frequency regulation, series application, wireless power charging, etc. For NAL certification there are product category change, Satellite Internet equipment and Functional virtualization device introduction. And there are China Energy Label (CEL) category update, China Cyber Security certification update, China RoHS test standards update, and more.

Criteria for Product Certification in Brazil – Inmetro vs. Anatel regulations

Walmir Macedo (CH Consulting)

There are basically two regulatory agencies overseeing the mandatory product certification landscape in Brazil. This presentation proposes to outline how Inmetro and Anatel work, and what an applicant in search of approvals for Brazil will have to learn in order to succeed in doing so.

India – TEC and Security Testing

Kapil Saproo (G&M Compliance, Inc.); **Thomas Ha** (G&M Compliance, Inc.)

We will present a new certification requirement for ITES products in India. The new certification is called TEC and the Indian authorities have also connected this with Security Testing. We will talk about the process of obtaining the certification, challenges and how G&M can support it.

Understanding PFAS: Regulations & Relevance for Companies

Eva Hink-Lemke (iPoint systems GmbH)

Per- and polyfluoroalkyl substances (PFAS) are a large class of thousands of synthetic chemicals that are used throughout society. However, they are increasingly detected as environmental pollutants and some are linked to negative effects on human health. Restrictions on PFAS has been set into force over the last months in several countries or local regions. The EU is working on massive restrictions for these substances that are affecting many products for industry and consumers. The presentation will outline the latest developments in the field of PFAS on a global level for the important markets. It will review the upcoming requirements, and support understanding the challenges and opportunities for industry operators.

Vietnam MIC regulation and updates

Nancy Lin (CSA Group)

Wondering how to access to Vietnam market for Information and Communications Technology (ICT) products? This presentation introduces MIC regulation for ICT products including safety, EMC and Radio requirements. It also explores upcoming changes in 2024.

GLOBAL MARKET ACCESS: ACCEPTED TO WAITLIST

Global Summary of WiFi 6E, 7 and Wi-Fi Type Approval Requirements

Peter Grinager (Approve-IT Inc.)

We'll summarize where the technologies are authorized for use, trends and themes around the technologies and how they are treated by regulators, detailed country specific profiles on Argentina, Brazil, the EU, Japan, Korea, UAE and the US, and a look where the technologies are expected to be adopted next.

Importing to India: Navigating TEC, BIS and other thrills

Lars Mellander (Nemko)

A general overview of access to the India marketplace with a specific focus on TEC. Presentation includes the intent of TEC/BIS, Best practices and the common frustrations that may or in many cases cannot be avoided. Presentation to include a number of key points/items that you must be aware of prior to determining if TEC and or BIS is realistic for your company.

Global Labeling Requirements

Theresa Glenna (TUV SUD)

Labeling has been one of the most challenging aspects of global compliance. Learn the minimum requirements for product compliance labels, e-labeling, and exceptions for small products.

CYBERSECURITY

Cybersecurity Testing and Certification of Consumer IoT Products in accordance with ETSI/EN 303 645

Sean McMahon (Nemko)

This presentation will explain the cybersecurity testing requirements in ETSI/EN 303 645 standard for consumer IoT, as well as Certification options available in industry. It will also discuss the upcoming mandatory Cyber requirements in the EU/RE Directive and how ETSI/EN 303 645 can prepare for these upcoming mandatory requirements.

Cybersecurity Regulations Evolution in Latin America

Elizabeth Perrier (ORBIS Compliance)

Cybersecurity regulations landscape is very active and ORBIS is tracking all the changes and impact to manufacturers. The presentation will provide a summary of all the active regulations across the continent and its implementation impact to product categories.

What is a “cyber device”?

Anura Fernando (UL Solutions); **Ravi Sharma** (UL Solutions)

Legislation that came into effect late last year has introduced a new term into the lexicon of medical device manufacturers: “cyber device.” This presentation will examine how this term came to exist in U.S. legislation and what kinds of technical issues medical device manufacturers will need to consider as they develop their own products within the confines of this new legislation and new terminology.

Consumer Cybersecurity, a piecemeal of regulations/standards and amalgamation of requirements

Ravi Sharma (UL Solutions)

The only constant that comes with cybersecurity is CHANGE! Each country and region is rushing towards formulating its cybersecurity regulations, making geographic expansion a big challenge for consumer device manufacturers. Even though there are overlapping cybersecurity requirements across these regulations and standards, a lack of harmonization exists.

What ISO 27001 can do for you: A Summary of the Main Benefits of Implementing an ISMS

Sean McMahon (Nemko)

ISO 27001 is the leading standard for information security management systems (ISMS). This presentation will show how ISO 27001 can help you: Prove your security and compliance, differentiate you from your competitors, reduce complexity and cost, improve structure and focus, reduce errors and save time. We will also share experiences and tips for ISO 27001 certification.

REGULATORY JEOPARDY

Regulatory Jeopardy

Regan Arndt (Thermo Fisher Scientific)

This year, everyone can join the fun with 'Regulatory Jeopardy' as a plenary session, where contestants and their team will race against the clock to answer thought provoking & challenging questions related to the complex world of Regulatory Compliance. Will you win this year's prize?

LEGAL

Mission: Impossible Distinctions – Cracking the Code of Intended, Foreseeable, and the Unbelievably Unpredictable in Product Compliance

Susanne Wende (Hochschule München)

All European Product Compliance concepts of liability refer to intended use, foreseeable use and misuse of products. The distinction is a challenge which can only be mastered with technical and legal expertise. Slightly different wordings in product liability and product safety law bring additional complexity to the interpretation of the relevant provisions. A consistent approach is necessary in order to keep the law applicable, now more than ever because the distinction will also be implemented for ecodesign law and the AI Act in the European Union. The session will shed some light on possible interpretations and how to deal with the challenge in practice.

Customer Call Centers – Risk and Reward

Ted Dorenkamp (Bowman and Brooke LLP)

Customer feedback is another data point companies use to evaluate and improve product quality and customer experience. But once customers get beyond the automated answer generators, talking to a customer service agent can expose companies to a whole host of legal and regulatory risks they should be prepared to accept and field. This session will discuss what companies should consider in developing a customer call center system.

Navigating through legal vs ethical dilemmas in product safety compliance: An audience discussion

James Bender (Intertek); **Arun Kapoor** (Noerr); **Ted Dorenkamp** (Bowman and Brooke LLP)

Legal vs ethical product safety compliance challenges often arise during product design and development as well as post-sale monitoring and market performance. Often but not obvious uncertainties in the product development process are influenced by legal vs. ethical obligations. This session provides an exciting panel led audience discussion identifying anticipated challenges and tools to mitigate such challenges.

Legal track open panel discussion

Arun Kapoor (Noerr); **Ted Dorenkamp** (Bowman and Brooke LLP)

Our legal track open panel discussion will give all those in attendance the opportunity to bring up any discussion topics from the day; in addition, any discussion topics impacting our attendees can be discussed in this open forum. The panel of experts will start with some 'door openers' to get the discussion going, and we are sure that we will have a lively discussion for this session.

LEGAL (CONT'D)

The European Batteries Regulation – Supercharged with requirements on energy storages.

Ulrich Spiegel (Taylor Wessing)

Energy storage systems are in vogue, especially considering the so-called green transition. With the EU Batteries Regulation, the EU stipulates comprehensive safety and sustainability requirements for these systems. In future, battery law will no longer “only” be waste-related environmental law; it takes step to life cycle-related regulation focusing on reuse.

Product Compliance 3.0 – Raw material and supply chain compliance in Europe

Arun Kapoor (Noerr)

In the 2000s, EU product legislation related almost exclusively to the safety of products. In the 2010s, more and more environmental requirements were included. Currently, product compliance in Europe is developing into raw material and supply chain compliance. The example of the European Deforestation Regulation (EU) 2023/1115 shows that the marketability of a product can no longer be tested exclusively in the laboratories.

ENVIRONMENTAL, SUSTAINABILITY, GOVERNANCE

Environmental, Social, and Governance 101

Jamie Wallisch (Assent); **Neil Smith** (Assen)

Sustainability, ESG, GHG emissions, forced labor, supply chain resiliency: all these concepts surround us in our world today with ambiguous definitions and little context. In our presentation, we seek to level-set on the current state of ESG matters for durable goods manufacturers, reviewing the strategic compliance needs and due diligence efforts to institute in your companies programs to satisfy market pressures and continue to have optimal market access. This session will review what is ESG, why is the concept of ESG vital to growing compliance programs in house, and the current standards, frameworks, and regulations that would be a top priority for manufactures today.

Environmental, Sustainability, Governance – an Overview

Aurelien Hathout (Enviropass Expertise Inc.)

Electronic Environmental Compliance is vital for sustainable technology. Rigorous adherence to legal requirements worldwide ensures minimal impact on the environment. Compliance addresses hazardous materials, energy efficiency, and responsible disposal with: RoHS, REACH, California Proposition 65, Conflict Minerals, TSCA-PBT, Ecodesign, PFAS, and others. This presentation will introduce you to them.

The PFAS Challenge – Supplier info, analytical testing and database tracking

Ken Kapur (Thermo Fisher Scientific)

The PFAS Challenge – Supplier info, analytical testing and database tracking. This presentation will cover the industry challenges related to PFAS. PFAS represents Per- and Polyfluoroalkyl Substances and new restrictions are being established to protect drinking water and human health. Based on the new and emerging regulations, the industry has to deal with new challenges as specified by the EPA, the EU and other regions around the world. This talk will look at best practices and the optimal methods for collecting supplier information, conducting analytical testing and tracking PFAS data in a database.

Mounting pressure on standardizing ESG regulations: Deep Dive into CSRD and CS3D

Jamie Wallisch (Assent)

Throughout the last two years, the European Union and the European Commission have taken impressive strides towards tangible regulations in the ESG and sustainability space. The two regulations with the most broad-sweeping scopes and impacts in the near-future include the Corporate Sustainability Reporting Directive (CSRD) and the Corporate Sustainability Due Diligence Directive (CS3D). Both these pieces of legislation are ESG-centric, seeking to standardize and create conformity of either process of due diligence for ESG activities (CS3D) or the reporting framework of sustainability activities (CSRD). In this session, the speakers will cover the structure of these regulations and their relationship, how these directives are significant and spearheading a new age of ESG compliance, and efforts companies can incorporate into their programs to achieve overall success.

ENVIRONMENTAL, SUSTAINABILITY, GOVERNANCE (CONT'D)

Current Trends for Eco-friendly Electronics – Case Studies

Aurelien Hathout (Enviropass Expertise Inc.)

Eco-friendly electronics are trending towards sustainable materials, energy efficiency, and circular design. More than ever, manufacturers prioritize reduced environmental impacts, recyclability, and ethical sourcing. For example, product life cycle assessments, modular designs, and repairability have gained popularity. With case studies, this presentation will illustrate eco-conscious tech innovations and best practices.

EU Battery Regulation and ESPR

Neil Smith (Assent); **Jamie Wallisch** (Assent)

Traditional market access requirements have largely focused on materials restrictions, safety, compatibility, and performance. Now, in the modern materials compliance market, we are observing a shift around the expectations to understand what materials are present but also the life cycle of the product as a whole, from sourcing to recyclability. This session will explore the convergence of areas of material compliance and the current expectations of raw materials due diligence. We will also discuss the content of these regulations and guidance on the engagement with them.

TSCA PFAS and Reporting Requirements

Santhanand Shanmugam (iLenSys Technologies Pvt. Ltd.)

To share the knowledge on PFAS and its application. EPA TSCA PFAS reporting requirements, scope and strategy with timeline.

ENVIRONMENTAL, SUSTAINABILITY, GOVERNANCE: ACCEPTED TO WAITLIST

Forced Labor Trends, Pressures, and Strategies

Jamie Wallisch (Assent)

The efforts to combat forced labor and remove it from companies supply chains is not a new concept. This has been an ever-evolving topic for nearly a 100 years. But over the past few years with the implementation of regulations like the Uyghur Forced Labor Prevention Act (UFLPA), the expectation of due diligence and presenting proof of no wrongdoing from companies has shifted the way the market, government enforcers, and customers all engage with the topic. This session will review the latest international forced labor regulations, the mounting pressures these laws seek to create, and the various strategies companies can take to deal with the growing expectations in a manageable way.

The Constantly Evolving PFAS Requirements

Aurelien Hathout (Enviropass Expertise Inc.)

Per- and poly-fluoroalkyl substances, also known as PFAS, are everywhere... It includes electronic applications. Because of health and environmental concerns, PFAS regulations are emerging in mature markets. New obligations to manufacturers and announcements are developing fast. Let us look at the current situation and discuss a practical strategy for compliance.

GLOBAL HAZARDOUS LOCATIONS

Differences in how U.S. ANSI HazLoc and Global IEC Ex standards approach safety

Steve Blais (Emerson/Appleton Group); **Erin LaRocco** (UL Solutions)

Division 1 explosionproof and Zone 1 flameproof equipment are designed, tested, and manufactured to comply with multiple global product safety standards and systems for hazardous locations/explosive atmospheres. This presentation will highlight the differences and commonalities of these requirements for equipment for U.S. ANSI Hazardous Locations and global IEC Ex Atmospheres equipment.

Preview of key 2026 National Electrical Code (NEC) public input

Joseph Wages Jr. (IAEI); **William Fiske** (Intertek)

Earlier this year, technical committees addressed public inputs submitted for the 2026 NEC. While the actions taken by these committees do not yet represent final 2026 NEC text, they provide an initial view into what could likely be final text. This presentation will preview key HazLoc and OrdLoc public inputs for the 2026 NEC.

High hazard fire & gas detection applications

Jon Miller (MSA)

Fire and gas detectors most certainly could be utilized in a variety of different ways for high hazard areas. The fire and gas detection capability can provide for both early warning mapping provisions in addition to alarming for safety purpose on a 24/7 basis.

Two Years On: Reflecting on Brazil's Updated Regulations for Ex Equipment

Jeff Iverson (CSA Group)

Two years after significant updates, this talk revisits Brazil's updated regulations for Ex equipment, highlighting key changes. We'll delve into Ordinance No. 115, which builds on the general requirements of Ordinance No. 200, examining the specific scope, updated certification processes, and responsibilities for stakeholders in comparison with the earlier Ordinance No. 179.

ATEX and IECEx Quality Assessment compared to OSHA NRTL factory surveillance

Frederick Kiddle (ABB)

"Ex" conformity audits verify the effectiveness of quality management systems; whereas factory surveillances are programs implemented to satisfy OSHA's NRTL Directive. This presentation compares an ATEX "QAN" and IECEx "QAR" to NRTL programs for factory surveillance and will address recent changes to the OSHA Directive for acceptance of the IECEx.

MEDICAL

IEC 60601-1 Amd. 2, Main differences

Igor Duspara (Nemko USA, Inc.)

This presentation will delve into the main differences introduced in the recent publication of IEC 60601-1 Amd. 2.

Alarm System in Medical Electrical Equipment or Medical Electrical System

Liem Lam (CSA Group)

This paper introduces the IEC 60601-1-8 amendment 2 (AMD2:2020) expanding requirements related to volume and characteristics of auditory alarm signals such: signal pulse shape, rise/fall time, signal burst pattern, frequency range, and harmonics for the application of alarm systems and alarm signals in medical electrical equipment or systems.

The need for CMDI (Clinical Medical Device Information) - An Alert Signal

Steli Loznen (IEEE PSES)

All health professionals using thousands of medical devices and disposables are confronted with many unacceptable risks due to the absence of clear clinical medical device information (CMDI). For the use of medicines, the pharmacists find valuable help in the existing drug information. CMDI needs to play a central role in patient care by preventing numerous misunderstandings and failures. The information from User Manuals, Instruction for Use, etc.,

are not enough for well understanding of the medical devices about Usability, Residual Risks, Incompatibilities, and other points of view. This gap can be filled by the CMDI Data Base which needs to provide, by type of Clinical Applications, a true and responsible global image about a specific medical device.

Risk Management in Medical Devices: An application of ISO 14971

Kiki Yang (CSA Group)

This paper introduces ISO 14971's role in medical device risk management, highlighting its integration with standards like ISO 13485 and IEC 60601-1. It focuses on the complete risk management process, from analysis to post-production, underscoring its importance in ensuring medical device safety.

EMERGING TECHNOLOGIES AND INNOVATION

Safety Concerns for ITE in Immersion Cooling Systems

Ken Arenella (IBM)

An analysis of the specific safety concerns and requirements governing an immersion-cooled mainframe computer system. Material/Mechanical: (chemical safety, flammability, mechanical/weight, slip, drowning potential and requirements, material compatibility). System design requirements: (62368-1, clause G.15; hydrostatic testing, tubing and fittings, metal vs plastic parts, liquid pump requirements, hose flammability). Lab requirements for testing immersion-cooled system.

Evolution of Robot Safety – Including an Introduction to ANSI/CAN/UL/ULC 3300

Jason Smith (UL Solutions)

Robots are now being used in environments exposed to the general public, raising concerns about whether they can be trusted to operate safely around people. We will introduce safety standards used to address those concerns, including the new UL 3300, the standard for Service, Communication, Information, Education, and Entertainment Robots.

Virtual worlds: Introduction, technology and regulatory framework

Thomas Killam (OnRule)

In this presentation, we will provide an introduction to virtual world (Augmented Reality – AR/Virtual Reality – VR/Mixed Reality – MR/Extended Reality – XR), the market and the technology. Importantly, we will discuss the regulatory concerns, scope and framework of regulations. Lastly, we will discuss the efforts taking place to develop the required technical standards.

Quantum Computing & Information Supported Future Product Safety Requirements for 6G Advanced Mobile Systems

Minsoo Joo (Yonsei university); **Wonsuk Yoo** (Yonsei University); **Jong-Moon Chung** (Yonsei University)

In the era of 6G mobile systems, quantum computing and information processing will play a significant role in advanced devices, applications, and services. Product safety and compliance engineering standards need to be prepared for these new emerging quantum products and services. This presentation introduces the fundamental principles of quantum computing and security applications that use quantum technology focusing on future product safety and compliance engineering needs.

V2X Connected Vehicle Future Product Safety Requirements for Advanced Autonomous and Urban Air Mobility Vehicles

Wonsuk Yoo (Yonsei University); **Minsoo Joo** (Yonsei university); **Eunsu Lee** (Yonsei University); **Jong-Moon Chung** (Yonsei University)

Autonomous driving and urban air mobility (UAM) vehicles are the core entities that will drive the establishment of the intelligent transportation system (ITS) future. Considering the significant importance of passenger safety, the level of vehicle safety and compliance engineering regulations must be set extremely high. This presentation provides an overview of autonomous driving vehicles, connected cars, and UAM standards, including vehicle-to-everything (V2X) communication technologies, and proposes directions for future advancement.

Development of Laboratory Information Management System 4.0 (LIMS 4.0) in the TIC Industry through Industry 5.0 and CMMI assessment model

Chi Ho Li (Hong Kong Metropolitan University); **Fanny Tang** (Hong Kong Metropolitan University); **Ho Yin Yuen** (Hong Kong Metropolitan University)

The Testing, Inspection, and Certification (TIC) industry, being traditionally resistant to change, faces challenges in adopting Industry 5.0 (I5.0) applications. Most of the scholars focused on the I5.0 applications for enriching the productivity but seldom in product safety related research topics. This paper explores the development and integration of Laboratory Information Management System 4.0 (LIMS 4.0) as a solution to the slow progress in applying I5.0 concepts. The paper will delve into the difficulties in bringing about changes in the TIC industry, current assessment models, I5.0 concepts, and how LIMS 4.0, infused with assessment models, can ease the technology adoption challenges. Furthermore, a specific case study of LIMS 4.0 deployment in the TIC industry will be examined.

EMERGING TECHNOLOGIES & INNOVATION: ACCEPTED TO WAITLIST

Radar Systems in the Vehicular Environment

Tom Tidwell (Nemko)

The presentation looks at the past, present, and future use of radar systems in vehicular systems. What types of radar systems are used and what are the potential interference issues that exist in the vehicular environment?

EMC & WIRELESS COMPLIANCE

The Importance of Hearing Aid Compatibility Testing for Regulatory Compliance

Nima Molaei (Element Materials Technology); **Justin Chao** (Element Materials Technology)

This Presentation presents a comprehensive overview of hearing aid compatibility (HAC) in communication devices, focusing on the introduction, standardizations, and future prospects in ensuring accessibility for individuals with hearing impairments. It explores innovative strategies and best practices employed by manufacturers and stakeholders to navigate regulatory complexities and enhance HAC accessibility. By offering insights into the regulatory landscape surrounding HAC, this analysis aims to inform policymakers, industry professionals, and researchers, fostering collaboration towards the collective goal of promoting inclusive communication environments for individuals with hearing impairments.

The Next Step of Wi-Fi Evolution: Wi-Fi 6E(ax) / 7(be) + UNII4 + AFC

Juan Gonzalez (Nemko USA)

With the development of the new Wi-Fi 6E (802.11ax) and Wi-Fi 7 (802.11be) the efforts to ensure worldwide adoption, interoperability, and more secure and reliable technology, Wi-Fi 6E and 7 comes with a new element called Automated Frequency Coordination (AFC) System, where the AFC system automatically determines and provides lists of frequencies that are available for use by standard power access points operating in the 5.925-6.425 GHz and 6.525-6.875 GHz bands. Additionally, UNII4 (5.850-5.925GHz) band is now available which brings the possibility to accommodate an additional 160MHz channel for Wi-Fi 5GHz to deliver top performance.

Vehicle-to-Everything (V2X), the Future of Vehicle Communication

Tom Tidwell (Nemko)

This presentation explores the evolution of vehicle communication system technologies and their use in autonomous vehicles.

FCC RF exposure on URS (Unintentional Radiator Sources)

Juan Gonzalez (Nemko USA)

New RF exposure guidance in KDB 447498 will discuss provisions for evaluation of RF exposure contribution from Unintentional Radiator sources (URS) which will be a game changer since until now only Intentional radiators are required to meet RF exposure rules and traditionally EMC test data (Unintentional Emissions per FCC 15 B) has been used for addressing RFX compliance in digital devices without radios (known as unintentional radiators). These proposed changes on URS are based on the analysis of some special cases by the FCC where possible inaccuracy issues related to Part 15 Testing, especially on devices with Frequencies below 150KHz due near field effects and coupled devices affecting the matching impedance of the URS.

Radio Signal Management in a Medical Environment

Tom Tidwell (Nemko)

An investigation into intentional and unintentional signal management practices for medical facility environments.

EMC & WIRELESS COMPLIANCE: ACCEPTED TO WAITLIST

How to Have a Product Pass on the First Trip to the Lab

JAMES BACHER (JBRC Consulting LLC)

Only 10% of products pass on their first trip to safety and EMC labs with no changes. The first part of this presentation goes over how to move your products in to the 10% that pass with no changes, thereby avoiding delays in releasing products. The second part focuses on additional info to assist in passing the EMC tests.

FUNCTIONAL SAFETY

Functional Safety for Automation Technologies

Layne Lueckemeyer (CSA Group)

In the rapidly advancing field of industrial automation, functional safety presents complex compliance challenges. This presentation discusses comprehensive strategies and best practices for integrating safety systems into automation technologies, underscoring the vital role functional safety plays in elevating system reliability and improving operational standards in the industry.

Plugging into Safety: Addressing Functional Safety in eMobility

Layne Lueckemeyer (CSA Group)

Focusing on the critical role of functional safety in eMobility, this presentation examines essential standards, battery safety, and software integrity in electric vehicles. It highlights the integration of advanced technologies with safety standards to address the unique risks in the eMobility ecosystem.

Demystifying ISO 26262: An Automotive Functional Safety Case Study

Kevin Connelly (Horiba)

Learn core concepts, navigate ASIL levels, and gain practical insights for safety-critical automotive systems. This presentation will provide a walk through of the ISO 26262 evaluation process. Target Audience: Engineers, managers, and professionals involved in developing safety-critical automotive systems. Key Takeaways: Understand ISO 26262, implement safety measures, and achieve functional safety compliance."

AI in Automotive Functional Safety: Unveiling Emerging Techniques and Future Requirements

Kevin Connelly (Horiba)

As AI revolutionizes automotive technology, navigating functional safety becomes a critical challenge. This presentation explores cutting-edge techniques for integrating AI into safety-critical systems, while peering into the future of AI safety standards.

Target Audience: Automotive engineers, safety professionals, and AI developers working on safety-critical applications. Key Takeaways: Master essential techniques for responsible AI integration in functional safety contexts. Gain insights into emerging standards and potential regulatory frameworks for AI in automotive safety. Prepare for the upcoming evolution of ISO 26262 and its impact on AI development. Embrace the potential of AI while navigating the evolving landscape of automotive functional safety.

Beyond Functional Safety for Automated Systems

Jayalekshmi Krishnamoorthy (UL Solutions)

This presentation introduces the concept of Safety of The Intended Functionality (SOTIF) through the automotive standard ISO 21448. SOTIF addresses unreasonable risks due to hazards caused by functional insufficiencies and performance gaps in complex systems. It complements functional safety standards by going beyond risks caused through faults and malfunctions.

Creating Functionally Safe Software

Peter Brink (Underwriter Laboratories)

In this presentation, we will review the expectations for how to create software for use in safety critical systems. This entails two main things:

- 1) The use of a quality-based methodical software engineering process for managing the software development, specifically to minimize systematic error.
- 2) The use of safety analyses both to determine if there are gaps in the requirements coverage and if there is any possibility that non-safety related software can interfere with the critical software from performing its function.

OSHA

Enhancing Safety Compliance: Exploring the OSHA NRTL Program and Future Trends

Kevin Robinson (US Department of Labor – OSHA)

As we enter over five decades of OSHA's NRTL program, we will take a brief look back at the program beginnings, examine the changes over the last 50 years and discuss the requirements for equipment manufacturers, employers, and independent testing laboratories. The presentation will provide insights into the recent updates in the NRTL Directive and its alignment with ISO/IEC 17025 & ISO/IEC 17065 standards. We will also explore the impact of a global pandemic and increased utilization of remote/web based assessments and our planned changes for the future.